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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,573	02/28/2002	Theodorus Petrus Maria Schetters	I 2001.004 US	3895

31846 7590 09/09/2005

INTERVET U.S.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,573

Applicant(s)

SCHETTERS ET AL.

Examiner

Padmavathi v. Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 and 64-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: STIC error report.

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Detailed Action

Amendment

1. Applicant's amendment filed on 6/16/05 is acknowledged.

Status of claims

2. Claim 32 has been amended.

Claims 1-31, 36-63 and 68 are canceled.

Claims 32 and 64-67 are under examination.

Specification – Informalities withdrawn

3. In view of amendment, the examiner has withdrawn specification informalities for use of trademark.

Specification – Informalities maintained

4. The specification informalities made in the previous office action is maintained for the following reasons:

Applicant's amendment filed on 6/16/05 still contains a hyperlink (page 9, line 9) although applicant was advised to delete the embedded hyperlink. Applicant is again reminded that the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code see in particular at least page 9. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Specification – Informalities for Sequence disclosure: The specification pages 20, 21, 28 recite sequences that are not identified by the sequence identification numbers. Further, it is noted that the sequences in the figures are not identified by the sequence identification numbers. Therefore, applicant is advised to insert the sequences identification numbers either in the figures or in the brief description of the drawings.

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In response to the Office action, applicant inserted SEQ.ID.NO: 12, 13, 14 and 15 into the specification, and submitted a sequence listing for these sequences. However, it fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures (see Scientific and Technical Information Center (STIC) found errors when processing the computer readable form (CRF).

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

Claim Rejections - 35 USC 112, first paragraph withdrawn

5. In view of the amendment to the claim 32, and cancellation of claims, the written description rejection is withdrawn.
6. In view of the amendment to the claim 32, and cancellation of claims, the scope of enablement rejection is withdrawn.

Claim Rejections - 35 USC § 102 maintained

7. The rejection of claims 32 and 64 –67 under 35 U.S.C. 102(b) as being anticipated by Schetters et al 1992 (PARASITE IMMUNOLOGY 1992, 14(3) 295-305 abstract only) is maintained as set forth in the previous office action.

The rejection was on the grounds that Schetters et al disclose a vaccine comprising *Babesia* associated protein obtained from *Babesia canis* cultures and adjuvant (see abstract). In the absence of evidence to the contrary the disclosed prior art protein obtained from cultures comprises *B.canis* associated protein 15KD antigen comprising SEQ ID NO: 2 or immunogenic fragments of proteins that are 85%, 90% and 95% homologous to the amino acid sequence as depicted in SEQ ID NO: 2. Characteristic such as SEQ.ID.NO: 2 is considered as an inherent property of the disclosed vaccine comprising *B.canis* protein. Examiner is viewing the claims as having open claim language (i.e., comprising) Applicant's use of the open-ended term "comprising" in claims fails to include unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts). See *In re Horvitz*, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and *Ex parte Davis et al.*, 80 U.S.P.Q. 448 (PTO d. App.

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1948). In the absence of evidence to the contrary the disclosed prior art composition and the claimed composition are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed composition and the composition of the prior art. It is acknowledged that weight is given to every term in claims. This is why the instant claims drawn to pharmaceutical compositions and vaccine are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine compositions must be weighed with the structural limitations of the claim. If the vaccine compositions merely comprise a known composition comprising protein, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same composition comprising said protein as claimed. In re Thorpe, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). In re Marosi, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). In re Best, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). In re Brown, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972). Thus the prior art anticipated the claimed invention.

Applicant's arguments filed on 6/16/05 have been fully considered but they are not deemed to be persuasive.

Applicant states that the prior art proteins in the supernatant are exo-antigens and the claimed BcVir15 and HcVir15 are not exoantigens. The proteins in the supernatant are exo-antigen and are the subject of US patent 6,045,806. Applicant further describes the differences between the two proteins and states that the exo-antigens of the prior art are not recognized by an antiserum specific for 15kD antigen and brings examiner's attention to figure 8 and specification pages 29-30.

The examiner reviewed the suggested figures and specification and understands the applicant's invention. However, the examiner has rejected the claims based on the language and limitations (open language such as having and comprising) used in claim 32. As the claim recites an isolated protein "having" or "an amino acid sequence of SEQ.ID.NO: 2" ^{it} reads on the prior art exo antigen because applicant is claiming an isolated protein having an amino acid sequence ^{which is of} that SEQ.ID.NO: 2. Therefore, few amino acids of the prior art exo antigen, i.e., exo antigen read on the claimed invention and the specification on page 30 clearly stated that the anti-GST-ORF1 specifically recognized the 15 kD protein (Fig. 10 A, lane 2). In addition, the

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prior art exo- antigen has been shown to be more protective. Applicant is not claiming " An isolated Babesia canis associated protein, said protein having a molecular weight of about 15 kD ----- and comprising the amino acid sequence as depicted in SEQ.ID.NO: 2. Further, the limitations such as " Bcvir 15, antiserum specific for Bcvir 15, precipitated from total antigen fraction, etc-----." which applicant is arguing about are not set forth in the claims. Therefore, the rejection is maintained.

Remarks

8. No claims are allowed.

It is noted that the specification submitted is not clear and clean as several lines in the specification are unreadable and smudged out. Applicant is advised to submit a clean copy of the same.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives

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transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



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